

Application No.: 10/057,667
Amendment and Response dated December 27, 2004
Reply to Office Action of September 27, 2004
Docket No.: 760-12 DIV/RCE
Page 7

Remarks/Arguments:

Introduction

Claims 1-26 are pending. Claims 1, 8 and 17 are independent claims.

Summary of the Present Invention

The invention as presently defined by independent Claim 1 is directed to a method of making a tubular stent/graft assembly. The inventive method of Claim 1 comprises the steps of (i) forming a substantially planar strip and wire assembly comprising an essentially flat, planar graft strip formable into a graft and an essentially flat, planar stent wire formable into a radially adjustable stent, wherein said wire is attached lengthwise along the length of said planar strip and further wherein said graft strip is formed by extruding, casting or molding polymeric material; and (ii) helically winding said substantially planar strip and wire assembly to form said tubular stent/graft assembly. (emphasis added)

The invention as presently defined by independent Claim 8 is directed to a method of making a stent/graft assembly. The inventive method of Claim 8 comprises the steps of forming a substantially planar graft and stent material assembly comprising an essentially flat, planar graft strip and essentially flat essentially flat, planar stent material, wherein said graft strip is formed by extruding, casting or molding polymeric material; and winding said substantially planar graft and stent assembly to form said stent/graft assembly. (emphasis added)

The invention as presently defined by independent Claim 17 is directed to a method of making a tubular stent/graft assembly. The inventive method of Claim 17 comprises the steps

of (i) forming a substantially planar strip and stent assembly comprising an essentially flat, planar graft strip formable into a graft and an essentially flat, planar stent formable into a radially adjustable stent, wherein said planar stent is attached along the length of said planar strip and further wherein said graft strip is formed by extruding, casting or molding polymeric material; and (ii) helically winding said substantially planar strip and stent assembly to form said tubular stent/graft assembly. (emphasis added)

Thus, the independent claims of the present invention are directed to, *inter alia*, (1) firstly forming a planar stent-graft assembly strip and then secondly helically winding the strip to form a tubular stent-graft. The graft is of a nontextile construction.

Section 103 Rejections

Claims 1, 5, 6, 8-11, 14, 16, 17, 20, 21, 23, 24 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,824,040 to Cox et al. (hereinafter "Cox") in view of any one of U.S. Patent No. 6,488,701 to Nolting et al (hereinafter "Nolting"), U.S. Patent No. 6,143,022 to Shull et al (hereinafter "Shull") or U.S. Patent No. 5,527,353 to Schmitt (hereinafter "Schmitt"), either combined alone or optionally further taken with any one of U.S. Patent No. 5,226,913 to Pinchuk (hereinafter "Pinchuk '913"), U.S. Patent No. 5,163,958 to Pinchuk (hereinafter "Pinchuk '958") or U.S. Patent No. 5,092,87 to Pinchuk (hereinafter "Pinchuk '877"). Applicant respectfully traverses.

In brief, the Examiner alleges that one of ordinary skill in the art would arrive at the present invention, as follows:

The [Cox] reference suggested that those skilled in the art would have formed an essentially flat preformed assembly of a stent and a graft component and then helically wound the

same to form a stent graft assembly in tubular form. The [Cox] reference, however appears to have formed the strip of graft material from a woven strip of material onto which the stent component was secured with suture thread in operation. There is no indication that one skilled in the art would have formed the graft component from a strip of plastic material (like ptfe or e-ptfe tape of material.... Concerning the use of a tape of ptfe or e-ptfe in place of a woven strip of material ..., the reference to any one of Nolting ..., Shull ... or Schmitt ... are cited. ... [Further], the references to Pinchuk '913, Pinchuk '958 or Pinchuk are cited herein to show that ... the stent component was formed from a single undulating wire ... [which] was helically wound to form the prosthesis. (Office Action dated Sept. 27, 2004, pages 1-6) (emphasis added)

Applicant respectfully traverses.

Claims 1-24 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cox in view of any one of Nolting, Shull or Schmitt, either combined alone or optionally further taken with any one of Pinchuk '913, Pinchuk '958" or Pinchuk '877, further taken with either one of Shannon or Brauker.

In brief, the Examiner alleges that one of ordinary skill in the art would arrive at the present invention, as follows:

Cox et al is discussed in detail above. The [Cox] reference failed to expressly state that the wire component was the stent material and that the tape and/or strip material was the graft material. However, in the art of stent grafts, it was known at the time the invention was made to incorporate a wire component for the stent as well as a plastic (polyethylene terephthalate) as the graft component in the manufacture of a stent graft. Additionally, it was well known to embed the stent component within two layers of graft component material. Shannon et al as well as Brauker et al

Application No.: 10/057,667
Amendment and Response dated December 27, 2004
Reply to Office Action of September 27, 2004
Docket No.: 760-12 DIV/RCE
Page 10

evidence such. (Office Action dated Sept. 27, 2004, pages 6-7)
(emphasis added)

Applicant respectfully traverses.

Claim 25 is rejected under 35 U.S.C. §103(a) as being unpatentable over Cox in view of any one of Nolting, Shull or Schmitt, either combined alone or optionally further taken with any one of Pinchuk '913, Pinchuk '958 or Pinchuk '877, in further view of U.S. Patent No. 6,361,637 to Martin et al. (hereinafter "Martin").

In brief, the Examiner alleges that one of ordinary skill in the art would arrive at the present invention, as follows:

The references as set forth above in paragraph 2 [i.e., Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958" or Pinchuk '877,] suggested the overall arrangement for the stent graft, however they failed to teach that the stent wire material would have been formed from nitinol. However, in the art of making a stent graft assembly, it was known to provide the stent component as an undulated wire which was formed from nitinol as evidenced by Martin.... (Office Action dated Sept. 27, 2004, pages 8-9)

Applicant respectfully traverses.

In traversing the Section 103 rejections the Applicant will first describe the deficiencies of the individual cited references and will then describe the deficiencies of the various combinations of the cited references.

Cox:

Cox is directed to a prosthesis having diamond shaped elements 73 attached to a strip of woven liner material 75 by being stitched to form a ribbon. (Cox, column 12, lines 19-24). The ribbon is then wound over a mandrel to form the prosthesis. (*Id.*; Fig. 5E.). The diamond shaped elements 73 are formed from at least two wires that are diagonally disposed in a zig-zag manner across the width of the liner material 75. (See, Cox, Fig. 5E). The liner material is described as a woven material made from polyester or PTFE yarns. (Cox, column 12, lines 7-11). Such description is consistent with the surface markings shown on the liner material 75 in Fig. 5E. Thus, Cox describes a plurality diamond shaped elements being sewn onto a strip of woven material.

Further, Cox teaches that a stent or a stent-graft may also include strips of PTFE disposed over the stent. (See, Cox, Figure 5D). More specifically, Cox describes the strips of PTFE as being "a ribbed PTFE liner". (Cox, column 12, lines 16-18). Cox, however, fails to teach or suggest that the diamond shaped elements 73 or any other stent embodiments may be sewn onto or otherwise attached to such PTFE strips prior to the helical winding of such strips to form a tubular device. Thus, Cox recognized that stent-grafts may contain strips of PTFE, but Cox failed to teach or suggest that such PTFE strips may have stent wires sewn thereon, especially in a planar fashion prior to helical winding.

Moreover, in other embodiments, Cox fails to teach that other stent-grafts may be formed by helically winding planar stent-graft assemblies or are made from non-woven liners. In these other embodiments where Cox is silent on the particular construction details of its liner or graft materials, i.e., not specifically describing the graft yarns as being woven or ribbed PTFE, Cox teaches that its stent-grafts are formed from cylindrical grafts with cylindrical reinforcing elements being axially attached thereon. (See e.g., Cox, column 13, lines 6-26). Therefore, in its other embodiments Cox not only fails to teach or suggest the present

invention, but teaches away from the present invention as specifically teaching the use of tubular stent and/or graft components as contrasted from planar stent-graft assembly strips.

Nolting:

While not admitting that Nolting is prior art to the present invention, nevertheless Nolting also fails to teach or suggest the present invention. Nolting is directed to a stent graft, particularly one made from ePTFE tape. Nolting forms the stent graft as follows:

Specifically, a first tape is wrapped about the mandrel. Next, the stent is loaded onto the mandrel over the first tape. A second tape is then wrapped over the stent. (Nolting, column 8, lines 49-54)

Thus, Nolting teaches that grafts having strips of ePTFE are to be formed by first winding the ePTFE strips onto a mandrel, followed by loading a stent there over.

Shull:

While not admitting that Shull is prior art to the present invention, nevertheless Shull also fails to teach or suggest the present invention. Shull is directed a stent-graft. A tubular graft is made from helically winding ePTFE tape. The tubular ePTFE graft is then placed over a tubular stent to form the stent-graft. The method is quite complicated as the graft must be first made, then removed from a mandrel, and then positioned over a stent, as follows:

The method of manufacturing the assembly according to a first embodiment of the present invention comprises helically wrapping a polymeric tape around a mandrel. The tape is wrapped at a particular angle to the perpendicular axis of the mandrel in order to achieve the desired distensibility of the membrane. The method further comprises sintering the tape to itself over the mandrel under particular parameters to produce a thin tube with desired radial distensibility; removing the thin tube from the mandrel; covering the stent with the thin tube; suturing the graft to the stent; and

invertedly folding the ends of the graft over the ends of the stent. (Shull, column 5, lines 24-34) (emphasis added)

Thus, Shull teaches that grafts formed from ePTFE tape are to be formed by winding the tape onto a mandrel, followed by loading a stent there over.

Schmitt:

Schmitt teaches that a textile graft having a liner may be formed by winding tape material over a mandrel and positioning a tubular textile graft there over, as follows:

A composite soft-tissue prosthesis formed in accordance with the present invention may be made by first choosing a mandrel with an outside diameter corresponding to an inside diameter of a natural body lumen which is to be replaced. The mandrel preferably has a smooth outer surface. The liner may be produced from expanded PTFE film or other suitable polymer, which has been slit into a narrow tape (3-10 mm). The expanded PTFE tape is wound onto the smooth mandrel to form the liner. The textile substrate is made having an inner diameter close to the outer diameter of the expanded PTFE liner and is positioned over the liner while the liner is still on the mandrel. The entire assembly may be placed into an oven at a sufficiently high temperature to fuse the textile substrate to the polymeric liner. (Schmitt, column 7, lines 27-39) (emphasis added)

Alternatively, Schmitt teaches that the liner need not be made of tape, as follows:

An alternative method of making the composite soft-tissue prosthesis formed in accordance with the present invention includes forming a thin wall tubular liner by extruding a polymer. A textile substrate is made having an inner diameter close to the outer diameter of the polymeric liner. The textile sleeve is passed over the liner and heat conditioned to fuse the liner within the textile substrate.

Yet another method of forming the composite soft-tissue prosthesis formed in accordance with the present

invention includes dip-casting a polyurethane resin onto a mandrel to form the liner. The textile substrate is dimensioned to be passed over the dip-casted polyurethane liner. The composite structure is preferably heat conditioned to fuse the textile substrate to the polyurethane liner.
(Schmitt, column 7, lines 49-63) (emphasis added)

Thus, Schmitt teaches that lined grafts may be formed from an ePTFE tape by winding the tape onto a mandrel or alternatively forming a tubular liner directly on a mandrel, followed by loading a textile graft there over.

Pinchuk '913:

Pinchuk '913 is directed to a method of making a stent from an undulating wire. A generally planar, undulating length of wire is helically wound over a cylindrical mandrel to form the stent. (Pinchuk '913, column 5, lines 37-55). Pinchuk '913, however, fails to teach or suggest the use of a graft with its stent.

Pinchuk '958:

Pinchuk '958 is directed to a method of making a stent from an undulating, carbon-coated wire. A generally planar, undulating length of wire is helically wound over a cylindrical mandrel to form a carbon-coated stent. (Pinchuk '958, column 5, lines 8-33). Pinchuk '958, however, fails to teach or suggest the use of a graft with its stent.

Pinchuk '877:

Pinchuk '877 is directed to a method of making a stent from an undulating wire. A generally planar, undulating length of wire is helically wound over a cylindrical mandrel to form the stent. (Pinchuk '877, column 5, lines 18-54). Pinchuk '877, however, fails to teach or suggest the use of a graft with its stent.

Shannon:

The examiner cites Shannon for its teachings that a stent component may be disposed between two PTFE graft components.

Shannon, however, teaches that its tubular liner 12 must be first placed on a tubular mandrel 50, a tubular stent 14 is then disposed over the liner 12, and then the outer cover is disposed over the stent 14 by helically wrapping a tape 17 over the stent. (Shannon, column 10, line 50, to column 11, lines 13; and Figs. 4b-4f). The liner 12 is described as being formed by extruding PTFE through a tubular extrusion die. (Shannon, column 7, lines 32-35). The tape 17 is described as being formed by extruding PTFE through a film extrusion die. (Shannon, column 8, lines 13-17). Further, the stent is a braided stent having overlapping stent wires. (See e.g., Figs. 2 and 4c).

Thus, Shannon teaches a PTFE stent-graft is formed from an extruded tubular PTFE graft and a tubular stent, both of which are disposed over a tubular mandrel, followed by helically wrapping an extruded PTFE tape. Such teachings, however, are in direct contrast to the claimed recitations of the present invention.

Brauker:

The examiner cites Brauker for its teachings that a stent component may be disposed between two PTFE graft components.

While not admitting that Brauker is prior art to the present invention, nevertheless Brauker also fails to teach or suggest the present invention. Brauker forms its graft components by wrapping ePTFE graft material onto a mandrel (Brauker, column 9, line 66, to column 10, line 1; and column 10, lines 59-66) or by extruding tubular ePTFE onto a mandrel (Brauker, column 13, lines 13-47). Thus, Brauker forms a tubular ePTFE graft. A stent 80 is shown as

Application No.: 10/057,667
Amendment and Response dated December 27, 2004
Reply to Office Action of September 27, 2004
Docket No.: 760-12 DIV/RCE
Page 16

having an inner liner of such tubular-formed graft, an outer cover of such tubular-formed graft, or both.

Brauker, therefore, fails to teach or suggest the formation of a planar strip of stent-graft material as set forth in the present invention.

Martin:

The examiner cites Martin for its teachings that a stent may be made from nitinol and may have an undulated configuration.

Martin, however, specifically teaches that an undulating stent wire is to be helically wound around a mandrel to form its tubular stent. (Martin, column 13, lines 9-12). Graft material is also placed over a mandrel to form an inner tubular liner. (Martin, column 14, lines 4-6). The tubular stent removed from its mandrel and is then positioned over the inner liner, which is disposed over its mandrel, to form a stent-graft. (Martin, column 14, lines 8-10). A flat ribbon PTFE is then wrapped around the exterior surface of the stent. (Martin, column 14, lines 13-17).

Thus, Martin forms its prosthesis by individually placing different components of the prosthesis over a mandrel. Accordingly, Martin fails to teach or suggest the formation of an essentially flat, planar strip of stent-graft material as set forth in the present invention.

Applicable Law

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, it is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* Thus, the express

Application No.: 10/057,667
Amendment and Response dated December 27, 2004
Reply to Office Action of September 27, 2004
Docket No.: 760-12 DIV/RCE
Page 17

teachings of Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877, Shannon, Brauker and Martin, which would lead one away from the methods of the present invention, may not be ignored during examination.

Further, it is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art document or to combine documents to arrive at the claimed invention. The requisite motivation for relying upon the cited references and making the proposed combination must reference some teaching, suggestion or inference in the prior art as a whole, or from the knowledge generally available to one of ordinary skill in the art and not from Applicants' disclosure. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992).

Moreover, it is well established that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness and any attempt at hindsight reconstruction using Appellants' disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Independent Claims 1, 8 and 17 Are Patentably Distinct Over Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958 and Pinchuk '877

As discussed above, Cox fails to teach or suggest forming an essentially flat, planar assembly strip by, *inter alia*, forming the assembly strip comprising extruded, cast or molded polymeric graft material. The Action acknowledges that Cox fails to teach or suggest forming a planar assembly strip by, *inter alia*, forming the assembly strip comprising a non-textile graft material, such as extruded, cast or molded polymeric graft material, as the Action cites the secondary references for non-textile graft materials. The secondary references, however, all require that stent-grafts having non-textile graft portions be formed by methods in direct

contrast to the methods of the present invention, i.e. teach away from the present invention, as follows:

- (i) Nolting teaches the ePTFE tape is first wrapped about a mandrel, and then a stent is loaded over the wrapped tape. (Nolting, column 8, lines 49-54);
- (ii) Shull wraps ePTFE tape around a mandrel and forms a tubular ePTFE graft there over. The ePTFE graft is removed from the mandrel. The ePTFE graft is then positioned over a tubular stent to form a stent-graft. (Shull, column 5, lines 23-34);
- (iii) Schmitt teaches that a tubular liner is first formed on a mandrel either by wrapping ePTFE tape or by extrusion. A textile graft is passed over the liner to form a lined textile graft. (Schmitt, column 7, lines 27-63); and
- (iv) Pinchuk '913, Pinchuk '958 and Pinchuk '877 teach that a stent may be formed by helically wrapping an undulating wire, but fail to teach or suggest the use of a graft with the stent or a method for making a stent-graft. (Pinchuk '913, column 5, lines 37-55; Pinchuk '958, column 5, lines 8-33; Pinchuk '877, column 5, lines 18-54).

Such express teachings of Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958 and Pinchuk '877, which would lead one away from the methods of the present invention, may not be ignored during examination. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, the Examiner is prohibited against ignoring such contradictions while only picking portions that support the alleged rejections. *Id.*

Thus, the only teaching of forming an essentially flat, planar stent-graft assembly comprising an essentially flat, planar graft strip and an essentially flat, planar stent is Applicant's own specification, and any hindsight reconstruction of the cited references to present a *prima facie* case of obviousness is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Further there is no motivation to combine Cox with the secondary references (i.e., Nolting, Shull or Schmitt) or with the tertiary references (i.e., Pinchuk '913, Pinchuk '958 and Pinchuk '877). Cox recognized that its diamond shaped elements may be sewn onto the woven strip of planar graft material and recognized that stent-grafts may include strips of PTFE, but failed to teach that its diamond shaped elements or any of its other stent configurations may be attached to a planar strip or tape of PTFE. The secondary references fail to suggest stent elements may be attached onto strips of PTFE or even textile strips. The tertiary references fail to suggest the use of PTFE strips to form a stent-graft. Thus, there is not motivation in any of the references for one of ordinary skill in the art to combine the references to produce a stent graft as presently defined by the methods of independent claims 1, 8, and 17. Without some motivation to combine the references the Examiner has failed to present a *prima facie* case of obviousness.

Thus, Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958 and Pinchuk '877, individually or in any combination, fail to teach or suggest the present invention as presently defined in independent claims 1, 8 and 17. Reconsideration and withdrawal of the rejections of independent claims 1, 8 and 17, and all claims dependent therefrom, are therefore respectfully requested.

Independent Claims 1, 8 and 17 Are Patentably Distinct Over Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877, Shannon and Brauker

As discussed above, Cox fails to teach or suggest forming an essentially flat, planar assembly strip by, *inter alia*, forming the assembly strip comprising extruded, cast or molded polymeric graft material. The Action acknowledges that Cox fails to teach or suggest forming

Application No.: 10/057,667

Amendment and Response dated December 27, 2004

Reply to Office Action of September 27, 2004

Docket No.: 760-12 DIV/RCE

Page 20

a planar assembly strip by, *inter alia*, forming the assembly strip comprising a non-textile graft material, such as extruded, cast or molded polymeric graft material, as the Action cites secondary, tertiary and quaternary references for PTFE graft materials. As discussed above, the secondary references (i.e., Nolting, Shull or Schmitt) specifically teach the helical winding of PTFE tape to produce a tubular graft over a mandrel or a stent fail, and the tertiary references (i.e., Pinchuk '913, Pinchuk '958 and Pinchuk '877) fail to teach or suggest the use of graft strips with a stent. The quaternary references (i.e., Shannon and Brauker), however, also all require that stent-grafts having non-textile graft portions be formed by methods in direct contrast to the methods of the present invention, i.e. teach away from the present invention, as follows:

(i) Shannon teaches that a tubular liner must be first placed on a tubular mandrel , a tubular stent is then disposed over the liner, and then the outer cover is disposed over the stent by helically wrapping a tape over the stent (Shannon, column 10, line 50, to column 11, lines 13; and Figs. 4b-4f); and

(ii) Brauker forms its graft by wrapping graft material onto a mandrel or by extruding a tubular graft onto a mandrel (Brauker, column 9, line 66, to column 10, line 1; column 10, lines 59-66; column 13, lines 13-47).

Such express teachings of Shannon and Brauker, which would lead one away from the methods of the present invention, may not be ignored during examination. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, the Examiner is prohibited against ignoring such contradictions while only picking portions that support the alleged rejections. *Id.*

Thus, the only teaching of forming an essentially flat, planar stent-graft assembly comprising an essentially flat, planar graft strip and an essentially flat, planar stent is

Application No.: 10/057,667
Amendment and Response dated December 27, 2004
Reply to Office Action of September 27, 2004
Docket No.: 760-12 DIV/RCE
Page 21

Applicant's own specification, and any hindsight reconstruction of the cited references to present a *prima facie* case of obviousness is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Further there is no motivation to combine Cox with the secondary references (i.e., Nolting, Shull or Schmitt), the tertiary references (i.e., Pinchuk '913, Pinchuk '958 and Pinchuk '877) and quaternary references (i.e., Shannon and Brauker). Cox recognized that its diamond shaped elements may be sewn onto a woven strip of planar graft material and recognized that stent-grafts may include strips of PTFE, but failed to teach that its diamond shaped elements or any of its other stent configurations may be attached to a planar strip or tape of PTFE. The secondary and the quaternary references fail to suggest stent elements may be attached onto strips of PTFE or even textile strips. The tertiary references fail to suggest the use of PTFE strips to form a stent-graft. Thus, there is not motivation in any of the references for one of ordinary skill in the art to combine the references to produce a stent graft as presently defined by the methods of independent claims 1, 8, and 17. Without some motivation to combine the references the Examiner has failed to present a *prima facie* case of obviousness.

Thus, Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877, Shannon and Brauker, individually or in any combination, fail to teach or suggest the present invention as presently defined in independent claims 1, 8 and 17. Reconsideration and withdrawal of the rejections of claims 1-9, 11-24 and 26 are therefore respectfully requested.

Application No.: 10/057,667
Amendment and Response dated December 27, 2004
Reply to Office Action of September 27, 2004
Docket No.: 760-12 DIV/RCE
Page 22

Claim 25 Is Patentably Distinct Over Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877 and Martin

The action cited Martin for its teachings of an elongate undulating nitinol stent wire.

While Martin discloses an elongate undulating nitinol stent, none of the stent-grafts disclosed therein are produced in accordance with claimed recitations of the subject application. For example, Martin forms its stent-graft by placing graft material over a mandrel; winding a stent wire around a mandrel to form its tubular stent, and wrapping a flat PTFE ribbon around the exterior surface of the stent. (Martin, column 13, lines 9-12; column 14, lines 4-17).

Thus, Martin fails to cure the deficiencies of Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958 and Pinchuk '877. Additionally, the teaching of Martin and the teachings of the other cited references directed to the helical winding of ePTFE tapes to form a graft without having stent or wire components thereon before any helical winding may not be ignored by the Examiner. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Further, the Examiner is prohibited against ignoring such contradictions while only picking portions that support the alleged rejections. *Id.*

Thus, the only teaching of forming a stent-graft assembly comprising an essentially flat, planar graft strip of extruded, cast or molded polymeric material and an essentially flat, planar stent is Applicant's own specification and any hindsight reconstruction of the cited references to present a *prima facie* case of obviousness is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Application No.: 10/057,667
Amendment and Response dated December 27, 2004
Reply to Office Action of September 27, 2004
Docket No.: 760-12 DIV/RCE
Page 23

Thus, Cox, Cox, Nolting, Shull, Schmitt, Pinchuk '913, Pinchuk '958, Pinchuk '877 and Martin, individually or in any combination, fail to teach or suggest the present invention as presently defined in claim 25.

Therefore, reconsideration and withdrawal of the rejection of claim 25 are respectfully requested.

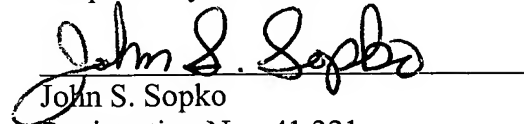
Summary

Therefore, Applicant respectfully submits that independent claims 1, 8 and 17, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461.

Respectfully submitted,



John S. Sopko
Registration No.: 41,321
Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700